DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2014

Ascension Orthopedics
% Mr. Frederic Testa
Regulatory Affairs Director
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K142413
Trade/Device Name: INTEGRA® TITAN™ Modular Total Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: September 15, 2014
Received: September 16, 2014

Dear Mr. Testa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142413

Device Name
INTEGRA® TITAN™ Modular Total Shoulder System

Indications for Use *(Describe)*
The INTEGRA TITAN™ Modular Total Shoulder System is a Total Shoulder Arthroplasty or Hemiarthroplasty which is indicated for: Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicated that alternative methods of treatment are unsatisfactory. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. – revision of a failed primary component) Shoulder Hemiarthroplasty is also indicated for: Ununited humeral head factures, Avascular necrosis of the humeral head, Rotator cuff arthropathy, Deformity and/or limited motion. The humeral component is intended for cemented or uncemented use. The glenoid component is intended for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

807.92(a)(1) – Submitter Information	
Name	Ascension Orthopedics, Inc.
Address	8700 Cameron Road, Suite 100 Austin, TX 78754
Name of Contact Person	Frederic Testa
Phone Number	(609) 936-3630
Fax Number	(609) 275-9445
Establishment Registration Number	1651501
Date Prepared	November 11th, 2014
807.92(a)(2) – Name of device	
Trade or Propriety Name	INTEGRA® TITAN™ Modular Total Shoulder System
Common or Usual Name	Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Classification Name	Prostheses, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Classification Panel	Orthopedic
Regulation	Class II (under 21CFR 888.3660)
Product Code	KWS, HSD
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
• Ascension® TITAN™ Modular Total Shoulder System (K112438)	

807.92(a)(4) - Device description

The TITAN™ Modular Total Shoulder System consists of a line of metaphyseal bodies, humeral stems, humeral heads and all polyethylene glenoid components. The body, stem and humeral head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement. The metaphyseal bodies and humeral stems are shaped to provide proximal fixation and optimal fixation area. Their variable length and proximally-filling shape are designed to accommodate the natural humeral geometry and provide stable fixation, proximal bone loading and proper head placement. The humeral heads are offered with both concentric and eccentric articulating surfaces. The humeral head may articulate against the natural glenoid bone, if it is of sufficient quality, or against the all polyethylene cemented glenoid. The glenoid has multiple options: keeled or standard pegged (3 pegs). All glenoid options are designed to function with both the concentric and eccentric heads.

The humeral components are intended for cemented or uncemented use, while the glenoid component is for use with cement only.

807.92(a)(5) – Intended Use of the device	
Indications for Use	The INTEGRA® TITAN™ Modular Total Shoulder System is indicated for use as a hemi or total shoulder replacement for:

	• Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis. • Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicated that alternative methods of treatment are unsatisfactory. • Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. – revision of a failed primary component) Shoulder Hemiarthroplasty is also indicated for: • Ununited humeral head factures • Avascular necrosis of the humeral head • Rotator cuff arthropathy • Deformity and/or limited motion. The humeral component is intended for cemented or uncemented use. The glenoid component is intended for cemented use only.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The INTEGRA® TITAN™ Modular Total Shoulder System is similar in design and materials to the predicate device, Ascension® TITAN™ Modular Total Shoulder System (K112438). The INTEGRA® TITAN™ Modular Total Shoulder System has similar indications for use, intended use and fundamental scientific technology as its predicate. The differences between the predicated and proposed device do not raise any new issues regarding safety and effectiveness; therefore, the INTEGRA® TITAN™ Modular Total Shoulder System is considered substantially equivalent to the predicate device.

807.92(b)(1-2) – Nonclinical Tests Submitted

Testing to verify the performance of the INTEGRA® TITAN™ Modular Total Shoulder System included the following:

- Taper Axial Disassembly Test
- Fatigue Test
- Maximum Static Load Test
- Impact Assembly Test
- Suture Verification Report

The results of these performance tests met their respective acceptance criteria and demonstrate that the INTEGRA® TITAN™ Modular Total Shoulder System is safe for the intended use, and is substantially equivalent to the predicate device identified.

807.92(b)(3) – Conclusions drawn from non-clinical data

The design features, materials, intended use, and overall fundamental scientific technology of the INTEGRA® TITAN™ Modular Total Shoulder System are substantially equivalent to the predicate device. The safety and effectiveness of the INTEGRA® TITAN™ Modular Total Shoulder System is adequately supported by the substantial equivalence information, materials information, and performance data provided within this Premarket Notification submission.